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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,595	11/30/2005	John Ong	0501-UTL-0	2750
44638	7590	11/20/2007	EXAMINER	
Intellectual Property Department			HARLE, JENNIFER I	
Amylin Pharmaceuticals, Inc.				
9360 Towne Centre Drive			ART UNIT	
San Diego, CA 92121			PAPER NUMBER	
			1654	
			MAIL DATE	
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			11/20/2007	
			PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Office Action Summary</b></p>	<b>Application No.</b> 10/559,595	<b>Applicant(s)</b> ONG ET AL.	
	<b>Examiner</b> Jennifer I. Harle	<b>Art Unit</b> 1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 November 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-25, drawn to a pharmaceutical composition for transmucosal administration of an exendin or exendin analog, comprising an exendin or an exendin analog.

Group II, claim(s) 26-27, drawn to a method for administration of an extending or an exendin analog.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: pharmaceutical exendins are known. See, e.g. US 2003/0087821, US 2002/0137666, US 6,767,887, US 6,703,359, US 5,424,286, US 5,846,937, WO 99/07404 A1, WO 99/40788 A1, DE 19921537, WO 00/66629.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Buffer: a single species from acetic acid, aminocaproic acid, or glutamic acid as recited in claims 4-5.

Cationic polyamino acid: a single species from poly-histidine, poly-arginine, poly-lysine or combination thereof as recited in claim 7.

Tonicifying Agent: a single species from sodium chloride, mannitol, sucrose, glucose and any combination thereof as recited in claim 17.

Viscosity-increasing Agent: a single species from hydroxypropyl cellulose, hydroxypropylmethylcellulose, methyl cellulose of average molecular weight between about 10 and 1,500 kDa, starch gums or any combination thereof as recited in claim 18.

Bioadhesive agent: a single species from carbomer, polycarbophil or any combination thereof as recited in claim 19.

Preservative: a single species from phenylethyl alcohol, methyl paraben, ethyl paraben, propylparaben, butyl paraben, chlorbutanol, benzoic acid, sorbic acid, phenol, m-cresol, alcohol, and any combination thereof as recited in claim 20.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

*Election of Peptide*

Additionally, Applicant is required to elect a single peptide as the peptide of the compound/composition of the method, as drawn to the elected invention, regardless of which group is elected. [Note: A generic (e.g. – peptide epitope, etc.) may NOT be elected as drawn to the elected invention because no meaningful search can be conducted without an undue burden, due to the myriad of potential substitution possible in each formula]. The peptides were not found to share a significant structural core from which a meaningful coextensive search could be conducted, thus a separate and distinct search, as well as examination, of each peptide sequence is required. See also MPEP 803.04 and/or 1850 [Note: All of the alternatives do not have a common property or activity. See references set forth above. Nor is a common structure present.] In order to effect a complete response to this Office Action, Applicant is required to elect a single peptide for examination and identify claims readable upon the elected peptide including any claims subsequently added. **This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each peptide is assumed to be a patentably distinct invention, in the absence of specific, substantial, and credible evidence to the contrary.**

4. The claims are deemed to correspond to the species listed above in the following manner:

Buffer - as recited in claims 4-5.

Cationic polyamino acid - as recited in claim 7.

Tonicifying Agent - as recited in claim 17.

Viscosity-increasing Agent - as recited in claim 18.

Bioadhesive agent - as recited in claim 19.

Preservative - as recited in claim 20.

The following claim(s) are generic: 1-27.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species do not share a significant structural core and the alternatives are not of a similar nature, i.e. sodium chloride is a salt while mannitol is a sugar and they are well known compounds.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.


Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is (571) 272-2763. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Jennifer I. Harle  
Examiner  
Art Unit 1654

November 15, 2007